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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Richard T. DEAN et al. Art Unit: 1811 #34
Serial No. : 08/236,402 Examiner: Davenport
Filed : 02 May 1994
Title : TECHNETIUM-99m LABELED IMAGING AGENTS

Assistant Commissioner for Patents
Washington, D.C. 20231

STATEMENT UNDER 37 C.F.R. § 1.608(a)

This statement accompanies a Request for Interference with U.S. Patent No. 5,759,516 filed concurrently herewith pursuant to 37 C.F.R. § 1.607.

The effective filing date of U.S. Patent No. 5,759,516 is 20 February 1992. Applicants have an earlier effective filing date, namely 27 November 1991.

Thus, applicants should be senior party in any such interference and there is basis upon which applicants are entitled to a judgment relative to the patentees.

Respectfully submitted,

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Date: 4 May 99

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REQUEST FOR INTERFERENCE WITH U.S. PATENT NO. 5,759,516

Applicants respectfully request that an interference be declared between the above-identified application and U.S. Patent No. 5,759,516. This application is currently involved in Interference No. 104,264.

Compliance with 37 C.F.R. § 1.607(a)

The information required by 37 C.F.R. § 1.607(a) is set forth under subheadings which correspond to the subsections of 37 C.F.R. § 1.607(a).

(1) Identification of the Interfering Patent: The patent which claims subject matter interfering with the subject matter claimed in the instant application is U.S. Patent No. 5,759,516 issued to Paul O. Zamora and Buck A. Rhodes and entitled

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"Peptide-Metal Ion Pharmaceutical Preparation". Said patent was issued on application No. 08/454,949 filed on 31 May 1995, which purports on its face to be a division of application No. 07/840,077 filed on 20 February 1992 (now U.S. Patent No. 5,443,816). Application No. 07/840,077 purports to be a continuation-in-part of application No. 07/565,275 filed on 8 August 1990 (now U.S. Patent No. 5,102,990, reissued as Re35,500 on 6 May 1997). Rhomed Incorporated of Albuquerque, New Mexico is the assignee named on the face of the patent. Copies of U.S. Patents Nos. 5,102,990, Re35,500, 5,443,816 and 5,759,516 are here enclosed as Appendices A, B, C and D, respectively.

Applicants acknowledge that Patentees Zamora and Rhodes would, in an interference involving their U.S. Patent No. 5,759,516 (hereinafter "the '516 Patent") be entitled to the benefit of the filing date of application No. 07/840,077 (hereinafter "the '816 Patent"). It is submitted, however, that in such interference, they would not be entitled to the benefit of the filing date of application No. 07/565,275 (hereinafter "the '990 Patent").

The '516 Patent is concerned with a peptide complex labelled with a metal ion, with the peptide itself comprising a biological-function domain and a metal ion-binding domain. The '990 Patent is concerned principally with methods for radiolabelling proteins. In the file of the '516 Patent, there is an office action dated 30 December 1996 in which the examiner states:

After re-examining Applicant's priority documents, Application Serial Nos. 07/840,077 [the '816 Patent] and 07/565,275 [the '990 Patent], the information disclosed in the present case was first disclosed in Application Serial No. 07/840,077; thus, Applicant's priority date is 2/20/92.

A copy of pertinent portions of the office action is enclosed as Appendix E. In a response filed on 5 May 1997, the applicants disagreed with the examiner's holding in this respect and responded that the term "antibody fragments" would be interpreted by a person of ordinary skill in the art as including both peptide and polypeptide fragments of antibodies. No other argument on this point was offered and the applicants did not point to any specific polypeptides which would fall within the definition of the peptides recited in their claims. A copy of pertinent portions of this response is enclosed as Appendix F. It is readily apparent that the specification of the '990 Patent does not comply with the requirements of 35 U.S.C. § 112 as supporting the claims of the '516 Patent.

(2) Proposed Count: Applicants propose a single count reading:

A metal ion-labelled peptide complex comprising:

- a) **a peptide including a biological-function domain and a metal ion-binding domain; and**
- b) **a metal ion complexed to the metal ion binding domain;**

wherein the metal ion-binding domain comprises one or more amino acids containing a sulfur atom which is available for

binding to metal ions or which can be made available for binding to metal ions, or comprises 2-mercaptoethylamine, 2-mercaptopropylamine, 2-mercaptoacetate or 3-mercaptopropionate, and further includes one or more amino acids each containing at least one nitrogen atom or oxygen atom but not a sulfur atom which is available for binding to metal ions or which can be made available for binding to metal ions;

wherein the biological-function domain is an amino acid sequence having a molecular weight of less than 10,000 daltons; and

wherein the peptide further comprises from 0 to about 20 amino acids not included within the metal ion-binding domain or the biological-function domain.

The proposed count is a phantom count prepared in accordance with MPEP Section 2309.01 (7th ed., July 1998) in order to encompass the broadest patentable interfering subject matter common to both parties.

In defining the "metal ion-binding domain", the sulphur-containing groups were expanded to include 2-mercaptoethylamine, 2-mercaptopropylamine, 2-mercaptoacetate and 3-mercaptopropionate, taken from applicants' application. In defining the biological-function domain, the term "containing from 1 to about 20 amino acids" was broadened to read "having a molecular weight of less than 10,000 daltons"; again, this changed language was taken from applicants' application.

As an alternative, a Count reading "**Claim 1 of Zamora or Claim 11 of Dean**" would be acceptable.

(3) Claims in the '516 Patent which Correspond to the Proposed Count: All of the claims in said patent correspond to the proposed Count.

(4) Identification of the Claims in Application No. 08/236,402 which Correspond to the Proposed Count: Claim 11 of application No. 08/236,402 corresponds substantially to the Count. In order to show this, there are attached hereto Appendix G, in which claim 11 is rewritten into independent form, and Appendix H which is a side-by-side comparison of the language of the proposed Count and analogous terms in claim 11.

It is believed that, of the claims currently in application No. 08/236,402, at least claims 1-3, 5-8, 12-17, 19-21 and 34-37 also would correspond to the proposed Count.

(5) Application of the Terms of Applicants' Newly-Presented Claims to Applicants' Disclosure: All of the claims which have been identified as corresponding to the proposed Count are already in this application.

(6) The Requirements of 35 U.S.C. § 135(b): The '516 Patent issued on 2 June 1998. Thus, the one-year period specified under 35 U.S.C. § 135(b) has not

yet run. Furthermore, all of the claims in the application identified as corresponding to the proposed Count were presented even before the issue date of the '516 Patent.

Applicants' Effective Filing Date is 27 November 1991

Accompanying this submission is a Statement under 37 C.F.R. § 1.608(a).

Applicants are entitled to the benefit of their application No. 07/807,062 filed on 27 November 1991, now U.S. Patent No. 5,443,815 (hereinafter "the '815 Patent"), a copy of which is here attached as Appendix I. This date is earlier than the effective filing date of the '516 Patent and, therefore, Applicants should be designated as senior party in the interference.

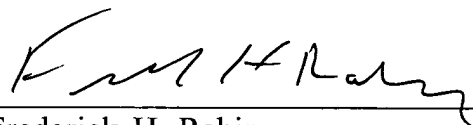
Applicants are currently involved in Interference No. 104,264 (hereinafter "the '264 Interference") with Zamora U.S. Patent No. 5,670,133 which has a common inventor with the '516 Patent and is believed to be co-owned therewith. Copies of pertinent pages of the Notice declaring the '264 Interference are here attached as Appendix J. The count of the '264 Interference includes claims 1, 7, 11, 14, 17, 34, 36 and 37 of the instant application; these are among the claims which would correspond to the Count of the interference now sought with the '516 Patent. In the '264 Interference, applicants were accorded benefit of the '815 Patent, and this benefit should also be applicable to the new interference. (In the '264 Interference, the time for filing a motion under 37 C.F.R. § 1.633(g) to attack the benefit of the '815 Patent

has passed and no such motion was filed on behalf of the opponent in that interference.)

A separate interference with the '516 Patent is being sought because the rules would not have permitted the addition of this patent to the '264 Interference by way of a Rule 633 motion.

Respectfully submitted,

Date: 4 May 99


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Enclosures: Appendices A-J
Statement under 37 C.F.R. § 1.608(a)

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